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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,763	11/28/2003	Ada S. Cowan	22,205	7216

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,763	COWAN ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-68 are pending.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in paragraph [0052]. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, **foreign application or patent, or to a publication** is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). It is emphasized that incorporation of a U.S. patent or application which itself incorporates "essential material" by reference, is also improper. See MPEP §608.01.

Claim Rejections - 35 USC § 112

Claims 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 and 68 depend from the method of claim 46 and further limit the steps of claim 46 to a composition. Methods are comprised or consist of steps, not components. The Examiner

respectfully suggests rewording claims 67 and 68 to read "the method according to claim 46 in which the composition prepared in step (a) consists essentially of..."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Thurston et al. (WO 00/66206).

Thurston discloses **therapeutic liquid compositions** for delivery to a user's aerodigestive system (i.e. including delivery to the pulmonary system) **via inhalation of an aerosol**, which may contain two or more basic components present in a variety of combinations, concentrations, and ratios to one another, wherein the first component is an **active ingredient**; the second component is a **carrier material (i.e. solvent)**; the third component is an aerosol property adjusting material; and the fourth optional component is at least one **excipient** (page 1, lines 14-16; page 3, lines 13-19).

Thurston discloses that in a preferred embodiment the composition are aerosolized using an electrostatic or **electrohydrodynamic (EHD) aerosol generating device** (page 4, lines 18-19).

Thurston discloses liquid compositions capable of: being aerosolized; **inhaled** by the user; **delivering** a predetermined dosage of a **active ingredient to the lungs** (i.e. pulmonary

delivery) of the user; and which are optimized for use with an **electrohydrodynamic (EHD)** aerosol generator (page 3, lines 13-16; page 4, lines 18-20).

Thurston discloses that one of the most important physical characteristics of the liquid composition includes its **surface tension**, which may vary from **10 to 72 milliNewtons/meter (i.e. 10 dyne/cm to 72 dyne/cm)** (page 6, lines 10-11). This surface tension range encompasses that stated in claim 1.

Thurston discloses that the aerosolized liquid composition **contains at least one active ingredient**, including **vitamins**, pulmonary surfactant, and antimicrobials, etc. (page 8, lines 1-16).

Thurston discloses that the choice of solvent is dictated by the solubility characteristics of the active ingredient and that **the active may be dissolved or suspended** (page 8, lines 26-29).

Thurston discloses that either water or **alcohol (i.e. ethanol)** is used as the solvent, and this carrier (solvent) may comprise **5-95% by volume of the composition** (page 8, lines 26-31).

Thurston discloses that (1) phospholipids are used as the carrier, in one embodiment, and (2) in another embodiment, perfluorinated compounds, including **perfluorooctanol** or **perfluorodecalin,** are **substituted for some or all of the** water or **ethanol** as the carrier material (page 9, lines 15-20).

Thurston teaches that the composition may also contain aerosol property adjusting materials, including, **propylene glycol, polyethylene glycol, glycerol, phospholipids, and perfluorocarbons** as (page 10, lines 18-22).

Thurston defines an excipient as "anything in a composition other than the active ingredient" (page 11, lines 13-14) and discloses that the liquid composition may include at least

one excipient, including: **lecithin, polyethylene glycol, ascorbic acid, antioxidants (e.g. Vitamin E, ascorbic acid, and ascorbic acid esters), benzalkonium chlorides, and parabens** (page 11, lines 27-31). Lecithin may also be used in the composition as a surfactant alone or with other surfactants (page 12, lines 19-27).

Thurston discloses that the composition may also contain ionic compounds, including **sodium chloride** (page 12, lines 15-18).

Thurston discloses other acceptable excipients, including: **polyvinyl pyrrolidone and polyvinyl alcohol** (page 12, lines 28-32). In exemplary composition 1-4, Thurston discloses compositions in which excipients are present in amounts ranging from 0.2% to 49%.

Although Thurston does not explicitly teach all the ranges stated for co-solvent, liquid fluorocarbon, phospholipid, and excipients, the Examiner contends that these ranges are inherently disclosed. This assertion is made based on the knowledge of the disclosed ranges of solvent and other components that may be used in the liquid composition and the understanding that it is well within the ability of a skilled artisan to deduce the quantities of the remaining components.

Claims 1-7, 13-29, 34-38, 40-42, 44-52, 57-61, and 63-68 rejected under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al. (U. S. Patent No. 5,733,939)

Fuhrman discloses **gaseous or liquid fluorocarbons** for the treatment of inflammation in various tissues (column 1, lines 9-12), including pulmonary tissue (column 2, lines 46-49). In other words the fluorocarbons also function as **active agents** (column 2, lines 42-46).

Fuhrman discloses an embodiment in which the fluorocarbon is administered into the lungs (i.e. pulmonary administration) (column 2, lines 59-62).

Fuhrman discloses that the fluorocarbon is a gas or liquid at room temperature (25 °C) and has from about 2-5 carbon atoms to about 10-14 carbon atoms (column 3, lines 56-59), for example, perfluorodecalin (column 3, line 65), **perfluorobutane, perfluoropropane, perfluoropentane, perfluorohexane, and perfluorooctane** (column 4, lines 8-9).

Fuhrman discloses that the fluorocarbons may be used as neat liquid compositions, gases, or as emulsions, especially **fluorocarbon-in-water emulsions** (i.e. including water as a solvent) (column 4, lines 42-44).

Fuhrman discloses that the emulsions typically include emulsifying agents, osmotic agents, **electrolytes (i.e. salts), and buffers (pH adjusting agents)**. The fluorocarbon concentrations may be as low as **5% w/v but may range up to 90%, 100%, or 125% w/v** (column 4, lines 50-52 and lines 55-59).

Fuhrman discloses that the preferred fluorocarbon emulsion formulations of U.S. Patent No. 4,865,836 (USPN '836) are incorporated by reference (column 4, lines 59-62). USPN '836 discloses **phospholipids**, specifically **lecithin**, as suitable emulsion surfactants and exemplary amounts of phospholipids are disclosed in Examples I (column 2, lines 60-62 in USPN '836).

Conclusion

The specification is objected. Claims 1-68 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni (Paddy) Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph. D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER